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Complications of intrastromal Corneal Ring Segments Implantation with Femtosecond laser for Channel Creation A Survey of 850 eyes with Keratoconus

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ABSTRACT

Purpose: To report the complications after implanation of intrastromal corneal ring segments (Keraring, Mediphacos, Belo Horizonte, Brazil) implantation in keratoconic eyes using a femtosecond laser (IntraLase, Advance Medical Optics, SA, USA) for channel creation.

Setting: Dunya Eye Hospital, Istanbul, Turkey.

Methods: Retrospective chart review of 531 patients (850 eyes) who had Kerraring, insertion using a femtosecond laser for channel creation. Intraoperative and postoperative complications were recorded.

Results: Intraoperatively, there were 22 (2.7%) cases of incomplete channel formation. The rest of the intraoperative complications were galvo lag error (system malfunction), [5 eyes, (0.6%)], endothelial perforation [5 eyes, (0.6%)] and incorrect entry of the channel [2 eyes, (0.2%)]. Postoperatively, there were eleven (1.3%) cases of segments' migration, 2 (0.2%) cases of corneal melting and one (0.1%) case of mild infection. The overall complication rate was 5.7% (49 cases out of 850 eyes).

Conclusions: Intracorneal ring segment implantation using a femtosecond laser for channel creation was related to a number of complications in this study. The most common complications were incomplete channel creation (intraoperatively) and segments' migration (postoperatively).

Key words: Intrastromal corneal ring segments, femtosecond laser, keratoconus

INTRODUCTION

The implantation of intracorneal ring segments is a minimal invasive surgical procedure for keratoconic (Kymionis et al. 2007) or post-LASIK ectatic (Kymionis et al. 2006) corneas. Before the introduction of femtosecond laser technology, channel creation was accomplished manually using mechanical devices (Ruckhofer et al. 2001; Kanellopoulos et al. 2006; Zare et al. 2007). This step of the procedure related with a number of possible complications such as epithelial defects, anterior or posterior corneal perforations, infectious keratitis, asymmetric segment placement, corneal stromal edema around the incision, extension of the incision towards the central visual axis or the limbus and persistent incisional gapping (Ruckhofer et al. 2001; Kanellopoulos et al. 2006; Zare et al. 2007). Recently, channel creation is performed using the femtosecond laser, which can deliver energy accurately to a precise depth in a programmed way. Studies indicate that Intacs implantation using a femtosecond laser is a safe and effective procedure for treating keratoconic corneas (Ratkay-Traub et al. 2003; Carrasquillo et al. 2007; Ertan et al. 2006; Ertan & Bahadir 2007; Ertan et al. 2007; Coskunseven et al. 2008; Sugar 2002; Shabayek & Alio 2007). The femtosecond laser minimizes procedure time and decreases the risk of inflammation or infection.

There are several different types of intracorneal rings, with varying curvature, width and zone of implantation. The Keraring (Mediphacos, Belo Horizonte, Brazil) is a newly developed implantable intrastromal corneal ring segment made of PMMA and is characterized by a triangular cross section that induces a prismatic effect on the cornea. The Keraring's apical diameter is 5 mm and the flat basis width is 0.6 mm with variable thickness (0.15 to 0.30 mm thickness with 0.5 mm steps) and arc lengths (90°, 160° and 210°).

To our knowledge, this study is the first large clinical trial for the complications of this type of intracorneal ring segment using the femtosecond laser for channel creation in keratoconic patients.

METHODS

Eight hundred fifty eyes (531 patients) with mild to moderate keratoconus underwent intrastromal corneal ring segment implantation (Keraring, Mediphacos, Belo Horizonte, Brazil), using a Femtosecond laser (IntraLase, Advanced Medical Optics, Santa Ana, California, USA) for channel creation. Prior to their operation, all patients gave informed consent in adherence to institutional guidelines and the tenets of the Declaration of Helsinki.

A complete ophthalmologic examination was performed preoperatively, including uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, biomicroscopy, corneal topography [Orbscan IIz (Bausch & Lomb, Rochester, NY), WaveLight Allegretto Topolyzer (WaveLight Laser Technologie, Erlangen, Germany)] and endothelial cell density measurement with specular microscopy (Konan Specular Microscope SP 9000 Noncon Robo Pachy Konan Medical Inc. Hyogo, Japan).

All patients had clear central corneas without scars and were contact lens intolerant. Corneal thickness was at least 350 µm at the tunnel location. Patients were excluded if any of the following criteria applied after the preoperative examination: history of herpes, keratitis, corneal dystrophies, diagnosed autoimmune disease, systemic connective tissue disease, acute or grade IV keratoconus, and endothelial cell count of less than 1000 cells/mm^2.

All procedures were performed under sterile conditions and topical anesthetic drops. The Purkinje reflex was chosen as the central point and marked under the WaveLight Allegretto Biomicroscope. A 5-mm marker was used to locate the exact ring channel. Corneal thickness was measured intraoperatively using ultrasonic pachymetry (Sonogage, Cleveland, Ohio, USA) along the ring location markings. Tunnel depth was set at 80% of the thinnest corneal thickness on the tunnel location. Arc length and thickness were chosen according to the manufacturer's nomogram. A 60 kHz femtosecond laser was used to create the ring channels. The channel's inner diameter was set to 4.4 mm, and the outer diameter was 5.6 mm. The entry cut thickness was 1 µm, and the ring energy used for channel creation was 1.30 µj. The entry cut energy was 1.30 µj and channel creation timing with the femtosecond laser was 15 seconds. The intracorneal ring segments were implanted immediately after channel creation, before the bubbles disappeared, as they revealed the exact tunnel location. To avoid any injury to the incision area, the segment was directly implanted with the special Keraring forceps.

Mean patients' age was 28.32 ± 7.28 (range, 18 to 44 years). Intraoperative and postoperative complications were recorded.

RESULTS

The overall complication rate was 5.7% (49 cases).

Intraoperative complications

Incomplete channel formation occurred in 22 eyes (2.6%). In these eyes channels were completed using a mechanical separator (Fig. 1).

Galvanometer lag error (system malfunction) occurred in 5 cases (0.6%). In all cases the error occurred two seconds before the completion of the incision. In two of the cases, the procedure was restarted and the error occurred again at the exact same time. A 30º knife was used then to complete the incision cut.

There were 5 (0.6%) cases of endothelial perforation, which were present intraoperatively as bubbles in the anterior chamber. In the first two patients, the ring was initially displaced, moving into the anterior chamber. In the third and fourth case, we recognized endothelial perforation during the channel creation .The channel was recreated with a targeted depth of 30 µm superficially than the original channel at the same time with the same vacuum. Edema was prevalent around the segment in these cases. In the last case the procedure was postponed for 1 month. Channel was recreated 90 µm superficially to protect the endothelium.

Incorrect entry of the channel was a complication that occurred in two eyes (0.2%) while using the 150 µm ring. A second channel was created using a mechanical separator.

Vacuum loss occurred in one eye (0.1%). Vacuum was created again at the same conjunctival and corneal plan and the same corneal marking was used. Channel was completed successfully at the same location and depth.

The overall intraoperative complication rate was 4.1% (35 cases).

Postoperative complications

Segment's displacement was observed in 11 cases (0.8%). In seven cases the segments migrated in the channel. A suture was placed in these cases at the incision and removed two months later, preventing any further migration. In four eyes there was a superficial movement of the segments (Fig 2). All of them were removed before corneal melting occurred.

Corneal melting (Fig. 3) was observed in 2 eyes (0.2%). In both cases corneal melting was noted above the segments because of the superficial placement of the rings and we performed a segment explantation with no further incidences.

There was one (0.1%) case of infection following implantation. The patient experienced corneal abscess formation at the incision site that was treated with intense antibiotics.

The overall postoperative complication rate was 1.6% (14 cases).

DISCUSSION

The first study ever published about segment implantation (Intacs) with the use of femtosecond laser, Ratkay-Traub et al (2003) reported no intraoperative complications and minimal deposits in the channels of two eyes (12.5%). Carrasquillo et al (2007) also reported no intraoperative complication during of femtosecond laser for channel creation. Postoperatively, 2 eyes (12.5%) developed corneal neovascularization and one eye (6.25%) had a fungal infection seven months after surgery. Ertan et al, in three studies of segment implantation with the use of femtosecond laser, had as the most common complications epithelial plugs in 15.2% (Ertan et al. 2006) and 24.6% (Ertan et al. 2007) of eyes while segments' migration occurred in three eyes (4.5%), (Ertan & Bahadir 2007).

In the only comparative study regarding INTACS inserts using the femtosecond laser or a mechanical spreader of Rabinowitz et al (2006) reported three (15%) patients had significant epithelial defects and one patient (5 %) with a gram-positive infection during the postoperative period in the femptosecond group. In the mechanical spreader group one patient (5%) had INTACS extruction due to superficial placement of the segment.

In other studies after segment implantation with the traditional mechanical method Kanellopoulos et al (2006) reported six (30%) cases of intracorneal ring segment movement and one (5%) case of corneal melt. As the most common complication, Ruckhofer et al (2001) reported corneal perforation in 4 (2.4%) eyes, while Zare et al (2007) reported segment movement and exposure in 3 (10%) eyes.

There are two studies regarding Kerrarings implantation using femtosecond laser for channel creation; Coskunseven et al (2008) reported no intraoperative complication and 3 (6%) cases of segment migration in 50 eyes, while Shabayek and Alió (2007) had one eye with infectious keratitis (4.8%) and eight eyes (38%) with incision opacification. In the current study, we had 33 (4%) and 14 (1.6%) complicated cases during or immediately after the procedure respectively. The discrepancy between the complication rates reported in the literature, is mainly due to variations in the number of studied eyes (in the current study we included 850 eyes) and difference in segments' characteristics (Intacs or Kerrarings).

Incomplete channel creation and segments' migration were the most common intra- and postoperatively complication respectively. Incomplete channel formation occurred in 22 (2.6%) eyes and all the procedures were completed with the use of a mechanical spreader. It is probably due to insufficient energy levels of the laser. This complication can be minimized by increasing the energy levels or by decreasing spot separation. Segments' displacement was observed in 11 cases (0.8%). In seven cases the segments migrate in the channel and a corneal suture placed at the incision site to prevent any further migration. In the other four eyes segments were moved superficially and were explanted before corneal melting occurred.

Galvanometer lag error is a technical problem of the device and it was noticed in 5 eyes (0.6%). The error is located at the memory system of the femtosecond which is unable to recall the operation center if this center is changed. In that case, a second channel has to be created next to the previous one. Additionally, the system does not have a separate incision cut program, therefore when the procedure is restarted, it begins with channel creation. To avoid the galvo error during channel creation, it is important to maintain the vacuum. If the galvo error does occur, the surgery should be postponed, and the second surgery should be performed with the same cone, (using a depth of 30 μm superficially). In case that galvo error is experienced during incision creation, the incision should be continued with a blade, even if there is only one second remaining. With the blade, another channel can be created above or below of the original plane immediately, before the bubbles disappear so that it is easier to locate the channel.

Endothelial perforation occurred in our study in five eyes (0.6%). It can be caused by incorrect preoperative pachymetry or deeper channels' creation. Femtosecond channel creation is very predictable but each cone has a 10-15 μm standard deviation. To avoid the incidence of endothelial perforation, it is important to achieve correct and accurate pachymetry in a 5-mm optical zone at the implantation site. The reference point should be the point of thinnest pachymetry at the channel locations. Endothelial perforation can be prevented by stopping channel creation as soon as the complication is recognized before the incision. Femptosecond channel creation is circular, rather than raster, starting from the central and continuing into the periphery. If bubbles are noted, and endothelial perforation appears to be the case, surgery should be postponed for at least one month. Then a new channel should be created 90 μm superficially to protect the endothelium (Kanellopoulos et al. 2006).

Incorrect entry of the channel occurred in 2 eyes (0.2 %). This complication may have been caused because we do not use a channel starter. In case of a surgeon's delay, the bubbles in the channel disappear. Therefore during the positioning of the segments a second channel in another corneal depth can be formed.

Postoperatively, corneal melting was noted in two eyes. Higher risk cases are those with superficial placement of the ring, patients with very thin corneas or after incorrect corneal pachymetry. In case of corneal melting, the ring has to be explanted immediately.

Vacuum loss occurred in one (0.1%) eye during channel creation. If vacuum loss occurs during incision it is possible to create the vacuum again at the same conjunctival and corneal plain, following the same marks to create the channel at the same location and depth. In case we preferred to continue with a diamond knife, the bubbles in the channel would be the reference point that would help us locate the channel more easily.

The most severe and potentially sight threatening complications were endothelial perforation (intraoperatively) corneal melting and infection (postoperatively), [0.9% (8 cases)].

Several potential limitations are apparent in this report, with the retrospective nature of the study and the absence of a comparative mechanical group and the visual - refractive outcomes of the participants to be the major reservations in order to conclude sufficient results.

In conclusion, we describe several complications of intrastromal corneal ring segments (Kerrarings) implantation with Femtosecond laser for channel creation. The most common complications were incomplete channel creation (intraoperatively) and segments' migration postoperatively.

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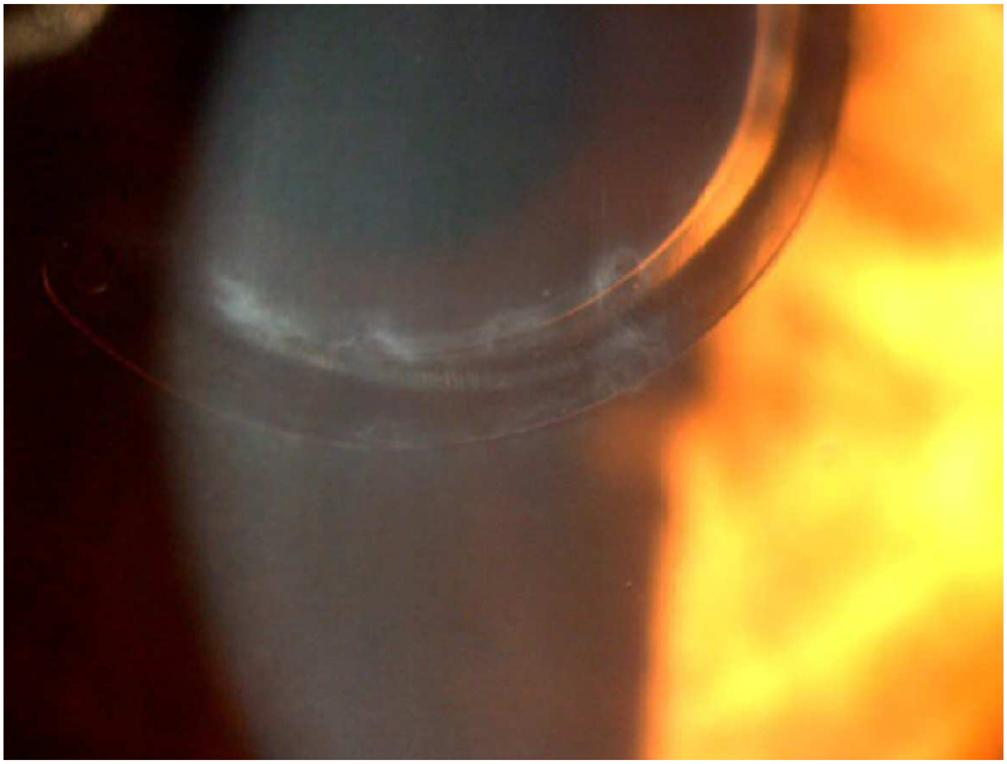
FIGURES

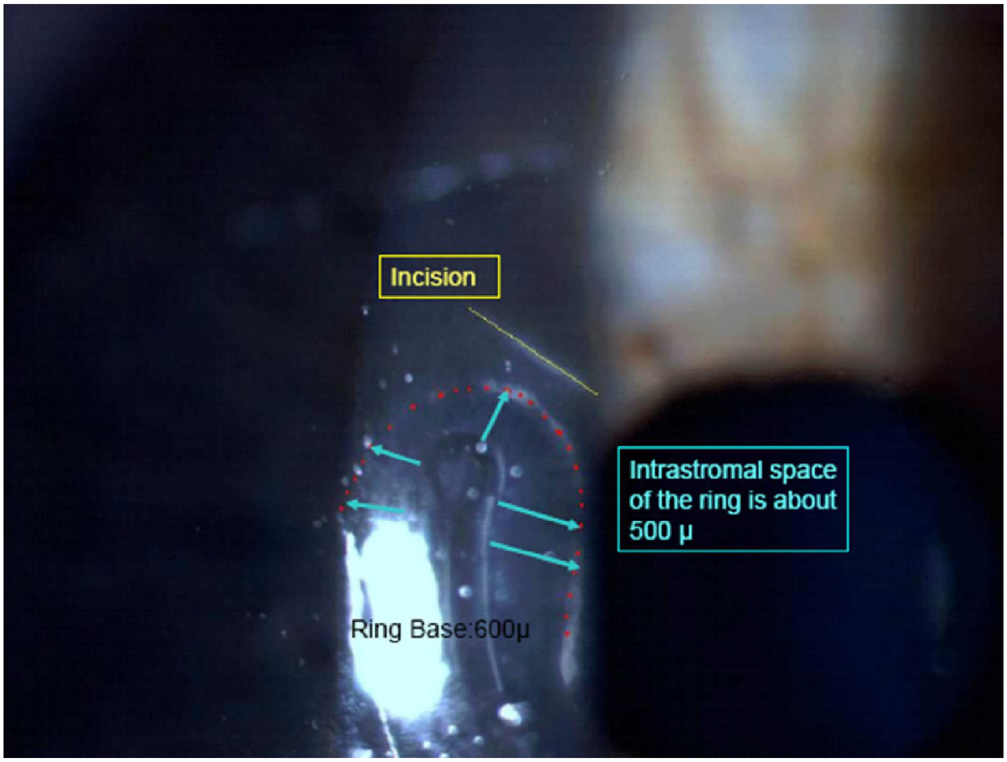
Figure 1: Incomplete channel formation: bridges around the segment. In these eyes channels were completed with a mechanical separator.

Figure 2: Segment develops empty space around itself. This is the first step before the superficial movement of the ring.

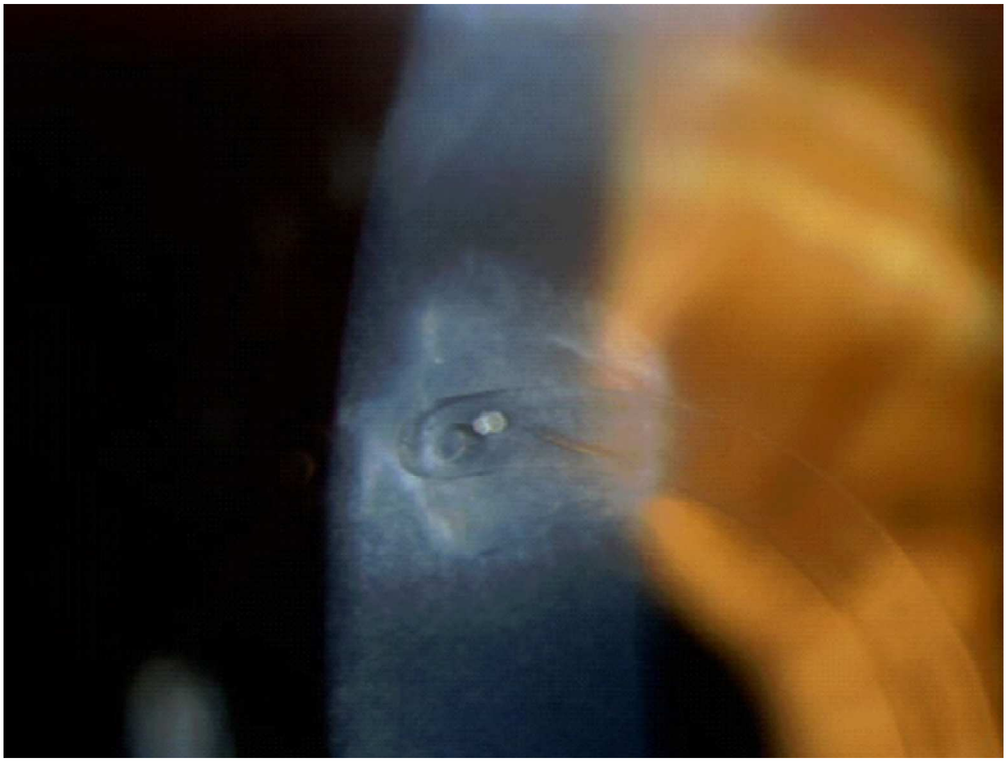
Figure 3: Corneal melting above the ring segment due to superficial implantation.



Incomplete tunnel formation: bridges around the segment. In these eyes tunnels were completed with a mechanical separator.
99x75mm (300 x 300 DPI)



Segment develops empty space around itself. This is the first step before the superficial movement of the ring.
489x369mm (300 x 300 DPI)



Corneal melting above the ring segment due to superficial implantation.
569x429mm (300 x 300 DPI)